

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

THE CLEVELAND CLINIC FOUNDATION) CASE NO.
9500 Euclid Avenue,)
Cleveland OH 44195, and) JUDGE
CLEVELAND HEARTLAB, INC.)
6701 Carnegie Avenue, Suite 500) **COMPLAINT FOR PATENT**
Cleveland, OH 44103) **INFRINGEMENT**
Plaintiffs,) (Jury Demand)
vs.)
TRUE HEALTH DIAGNOSTICS LLC,)
6170 Research Road)
Frisco, TX 75033)
Defendant.)

For their Complaint against True Health Diagnostics LLC, The Cleveland Clinic Foundation and Cleveland HeartLab, Inc. state as follows:

I. JURISDICTION AND VENUE

1. Counts I-III of this action arise under the Patent Laws of the United States, Title 35, United States Code. This Court has jurisdiction over Counts I-III under 28 U.S.C. § 1338(a).
2. Venue is proper in this district under 28 U.S.C. §§ 1391(d) and 1400(b).

II. THE PARTIES

3. Plaintiff The Cleveland Clinic Foundation (“CCF”) is a non-profit business organized and existing under the laws of the State of Ohio, with a principal place of business located at 9500 Euclid Avenue, Cleveland, Ohio 44195.

4. CCF is the owner of U.S. Patent No. 7,223,552 (“the ‘552 Patent”), U.S. Patent No. 7,459,286 (“the ‘286 Patent”) and U.S. Patent No. 8,349,581 (“the ‘581 Patent”) (Attached as Exhibits A, B, and C.)

5. Plaintiff Cleveland HeartLab, Inc. (“Cleveland HeartLab”) is a corporation organized and existing under the laws of the State of Delaware, and has a principal place of business located at 6701 Carnegie Avenue, Suite 500, Cleveland, OH 44103. Cleveland HeartLab regularly does business in this judicial district including selling, advertising and marketing its products and services within in this district, as well as maintaining a lab for blood testing services.

6. Cleveland HeartLab is the exclusive licensee of the ‘552 Patent, the ‘286 Patent and the ‘581 Patent, which are owned by CCF.

7. Defendant True Health Diagnostics LLC (“True Health”) is a limited liability corporation organized and existing under the laws of the State of Delaware, and has a principal place of business located at 6170 Research Road, Suite 211, Frisco, TX 75033. True Health regularly does business in this judicial district by selling and offering products for sale in this district, including the test kits and lab services that infringe the ‘552 Patent, the ‘286 Patent and the ‘581 Patent.

8. Upon information and belief, True Health also retains and maintains a sales agent in this district.

III. FACTUAL BACKGROUND

9. Physicians rely on lab tests to diagnose disease, guide treatment, and manage patient health risks. Particularly, blood tests are commonly used to test for Cardiovascular disease (CVD), which is the number-one killer of both men and women in the United States. While cholesterol is the most common test used to identify CVD risk, approximately 50 percent of people who have had a heart attack previously displayed normal cholesterol levels. Thus, there has been a glaring need for a test that is easy to administer, like a cholesterol test, but that provides better predictive data.

10. In 2003, researchers at CCF developed a new test for CVD risk that analyzes inflammation of the blood vessels—an actual symptom of CVD rather than a potential cause. This innovative test is called Myeloperoxidase or MPO. In order to protect its investment, CCF filed several patent applications relating to MPO and helped organize a group of local and national investors and physicians to launch Cleveland HeartLab in 2009 to further MPO testing.

11. Cleveland HeartLab, since its inception has worked to create and expand the market segment for MPO, to ensure proper use and quality of MPO testing and to continue MPO-related innovation. Cleveland HeartLab's efforts have included ongoing medical and scientific studies, pursuit of FDA approvals and Medicare reimbursement status, development and implementation of stringent manufacturing and quality standards, creation of dedicated educational programs and assembling of a well-trained sales, marketing and educational team.

12. As a result of these efforts, Cleveland HeartLab has grown from eight employees in 2009 to 140 employees today, including 30 employees dedicated to sales, support and education for MPO testing.

13. Cleveland HeartLab commercializes MPO by performing MPO tests directly for physicians and hospitals as well as offering MPO testing to otherwise competing laboratories. Some of these labs send patients' blood samples to Cleveland HeartLab for analysis. For others, Cleveland HeartLab manufactures and sells them high-quality MPO testing kits. Cleveland HeartLab's MPO customers include, for example, Quest Diagnostics, one of the largest laboratory services companies in the United States. In order to ensure quality control, Cleveland HeartLab imposes strict provisions on blood sample collection and has the right to reject specimens that were not properly collected.

14. In July 2010, Cleveland HeartLab entered into a "Laboratory Services Agreement" with Health Diagnostics Lab ("HDL"), a large laboratory services company. Under the Laboratory Services Agreement, Cleveland HeartLab performed all of HDL's MPO tests and reserved the right to reject blood specimens that failed to meet Cleveland HeartLab's standards.

15. During the summer of 2014, Chris Grottenthaler, CEO of Defendant True Health, contacted Cleveland HeartLab to discuss the potential purchase of MPO testing. True Health's

CEO subsequently visited Cleveland HeartLab for further discussions, but no agreement was ever reached.

16. HDL filed for bankruptcy in June of 2015. Shortly thereafter, HDL decided to put its assets up for sale via auction.

17. In July of 2015, True Health placed a bid in the HDL bankruptcy auction for certain HDL assets. In its bid, True Health expressly excluded Cleveland HeartLab's Laboratory Services Agreement with HDL for MPO testing. The bankruptcy court finally approved True Health's bid on or about September 16, 2015.

18. On or about September 14, Cleveland HeartLab CEO Jake Orville wrote a letter to True Health warning that any sale of MPO testing without authorization from Cleveland Heartlab would violate Cleveland HeartLab's patent rights. Cleveland HeartLab received no response to this letter.

19. In mid-October Cleveland HeartLab acquired a lab test result, dated October 5, 2015, printed on True Health letterhead, showing a test result for MPO. (Attached as Exhibit D.) Shortly thereafter, Cleveland Heartlab discovered two lab test results on HDL letterhead but dated after the asset purchase (October 3 and October 5, respectively). (Attached as Exhibits E and F.) These reports list the lab director as True Health COO and CSO Dr. Kent Mitchell and include testing for MPO. Cleveland HeartLab then uncovered a fourth report dated October 19, 2015, on True Health Letterhead, listing a MPO test result. (Attached as Exhibit G.)

20. Each of these lab reports includes an MPO risk range indicator. Exhibit D lists a high-risk MPO threshold of 640 pmol/L, with an optimal MPO range of 83-640 pmol/L. Exhibit E lists a high-risk MPO threshold of 400 pmol/L, an intermediate risk range of 321-399 pmol/L and optimal MPO range of 320 pmol/L. Exhibit F lists a high-risk MPO threshold of 332

pmol/L, with an intermediate risk range of 256-331 pmol/L and optimal MPO range listed as below 255 pmol/L. Exhibit G lists a high-risk MPO threshold of 557 pmol/L. Notably, each of these reports denotes a different risk range for MPO, casting serious doubt on the quality and accuracy of True Health's MPO tests.

21. Exhibits D, F, and G include a patient blood sample MPO test result that is compared to the MPO risk threshold denoted for that test to determine CVD risk.

IV. COUNT I: INFRINGEMENT OF THE ‘552 PATENT

22. Plaintiffs incorporate by reference herein the allegations of Paragraphs 1-21 of this Complaint.

23. CCF is the owner of the ‘552 Patent entitled “Myeloperoxidase, A Risk Indicator For Cardiovascular Disease.” The ‘552 Patent was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on May 29, 2007. Competitors have challenged the validity of the ‘552 Patent by filing two separate reexamination proceedings with the USPTO, Reexamination Request Nos. 90/009,501 and 90/009,744. The ‘552 Patent is still in effect and is presumed valid under the U.S. patent laws. A copy of the ‘552 Patent with its associated reexamination certificates is attached as Exhibit A.

24. True Health has been and still is directly infringing the ‘552 Patent under 35 U.S.C. § 271(a) by using MPO test kits and performing and/or selling MPO testing services that embody one or more claims of the ‘552 Patent. True Health will continue to infringe unless enjoined by this Court.

25. True Health has knowingly and willfully infringed the ‘552 Patent.

26. As a result of True Health's infringement of the '552 patent, CCF and Cleveland HeartLab have suffered monetary damages in an amount not yet determined, and will continue to suffer irreparable harm in the future unless True Health's infringing activities are enjoined by this Court.

27. CCF and Cleveland HeartLab will be greatly and irreparably harmed unless preliminary and permanent injunctions are issued enjoining True Health and their agents, servants, employees, attorneys, representatives, and all others acting on their behalf from infringing the '552 patent.

V. COUNT II: INFRINGEMENT OF THE '286 PATENT

28. Plaintiffs incorporate by reference herein the allegations of Paragraphs 1-27 of this Complaint.

29. CCF is the owner of the '286 Patent entitled "Assessing the Risk of a Major Adverse Cardiac Event in Patients with Chest Pain." The '286 Patent was duly and legally issued by the USPTO on December 2, 2008. The '286 Patent is still in effect and is presumed valid under the U.S. patent laws. A copy of the '286 Patent is attached as Exhibit B.

30. True Health has been and still is directly infringing the '286 Patent under 35 U.S.C. § 271(a) by using MPO test kits and performing and/or selling MPO testing services that embody one or more claims of the '286 Patent. True Health will continue to infringe unless enjoined by this Court.

31. True Health has knowingly and willfully infringed the '286 Patent.

32. As a result of True Health's infringement of the '286 patent, CCF and Cleveland HeartLab have suffered monetary damages in an amount not yet determined, and will continue to

suffer irreparable harm in the future unless True Health's infringing activities are enjoined by this Court.

33. CCF and Cleveland HeartLab will be greatly and irreparably harmed unless preliminary and permanent injunctions are issued enjoining True Health and their agents, servants, employees, attorneys, representatives, and all others acting on their behalf from infringing the '286 patent.

VI. COUNT III: INFRINGEMENT OF THE '581 PATENT

34. Plaintiffs incorporate by reference herein the allegations of Paragraphs 1-33 of this Complaint.

35. CCF is the owner of the '581 Patent entitled "Assessing the Risk of a Major Adverse Cardiac Event in Patients with Chest Pain." The '581 Patent was duly and legally issued by the USPTO on January 8, 2013. The '581 Patent is still in effect and is presumed valid under the U.S. patent laws. A copy of the '581 Patent is attached as Exhibit C.

36. True Health has been and still is directly infringing the '581 Patent under 35 U.S.C. § 271(a) by using MPO test kits and performing and/or selling MPO testing services that embody one or more claims of the '581 Patent. True Health will continue to infringe unless enjoined by this Court.

37. True Health has knowingly and willfully infringed the '581 Patent.

38. As a result of True Health's infringement of the '581 patent, CCF and Cleveland HeartLab have suffered monetary damages in an amount not yet determined, and will continue to suffer irreparable harm in the future unless True Health's infringing activities are enjoined by this Court.

39. CCF and Cleveland HeartLab will be greatly and irreparably harmed unless preliminary and permanent injunctions are issued enjoining True Health and their agents, servants, employees, attorneys, representatives, and all others acting on their behalf from infringing the ‘581 patent.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

- A. A judgment that True Health has directly infringed and continues to infringe the ‘552 Patent;
- B. A judgment that True Health’s infringement of the ‘552 Patent has been willful;
- C. A judgment against True Health awarding Plaintiffs damages suffered by Plaintiffs pursuant to 35 U.S.C. § 284 on account of True Health infringement of the ‘552 Patent;
- D. A judgment that Plaintiffs’ damages be trebled pursuant to 35 U.S.C. § 284 and that punitive damages be assessed against True Health;
- E. A Temporary Restraining Order and Preliminary and Permanent Injunctions against True Health and any entity acting in concert with True Health, pursuant to 35 U.S.C. § 283, preventing True Health and any such entity, from infringing the ‘552 patent;
- F. A judgment that True Health has directly infringed and continues to infringe the ‘286 Patent;
- G. A judgment that True Health’s infringement of the ‘286 Patent has been willful;

- H. A judgment against True Health awarding Plaintiffs damages suffered by Plaintiffs pursuant to 35 U.S.C. § 284 on account of True Health infringement of the ‘286 Patent;
- I. A judgment that Plaintiffs’ damages be trebled pursuant to 35 U.S.C. § 284 and that punitive damages be assessed against True Health;
- J. A Temporary Restraining Order and Preliminary and Permanent Injunctions against True Health and any entity acting in concert with True Health, pursuant to 35 U.S.C. § 283, preventing True Health and any such entity, from infringing the ‘286 patent;
- K. A judgment that True Health has directly infringed and continues to infringe the ‘581 Patent;
- L. A judgment that True Health’s infringement of the ‘581 Patent has been willful;
- M. A judgment against True Health awarding Plaintiffs damages suffered by Plaintiffs pursuant to 35 U.S.C. § 284 on account of True Health infringement of the ‘581 Patent;
- N. A judgment that Plaintiffs’ damages be trebled pursuant to 35 U.S.C. § 284 and that punitive damages be assessed against True Health;
- O. A Temporary Restraining Order and Preliminary and Permanent Injunctions against True Health and any entity acting in concert with True Health, pursuant to 35 U.S.C. § 283, preventing True Health and any such entity, from infringing the ‘581 patent;
- P. A judgment that True Health be directed to pay Plaintiffs’ attorney fees pursuant to 35 U.S.C. § 285 and costs incurred herein; and

Q. Such other and further relief as the Court deems just and equitable.

VIII. DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. Rule 38(b), Plaintiffs respectfully demand a trial by jury of all issues triable as of right to a jury.

Dated: November 12, 2015

Respectfully submitted,

s/Todd R. Tucker

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